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## (54) Pouch-like bags for contain- ing liquids

(57) A pouch-like bag (10) has two walls of flexible plastics sealed around their periphery, an elongate insert (14) capable of self-sealing a transverse puncture located adjacent to the bag periphery, and a tearable tag (11) which, when torn off, exposes a side of the insert which is preferably formed with a notch or groove to guide a needle for penetration transversely through the insert into the bag. The bag may also have a pair of inward extensions (19) of the peripheral seal (18) defining a passage (20) for guiding an administration needle into the bag, the passage having a frangible seal (21) at its inner end and being closed by a tearable tag (12) at its outer end. The walls are pre-

ferably laminated with the inner layer of linear low density polyethylene and the outer layer of oriented polypropylene.

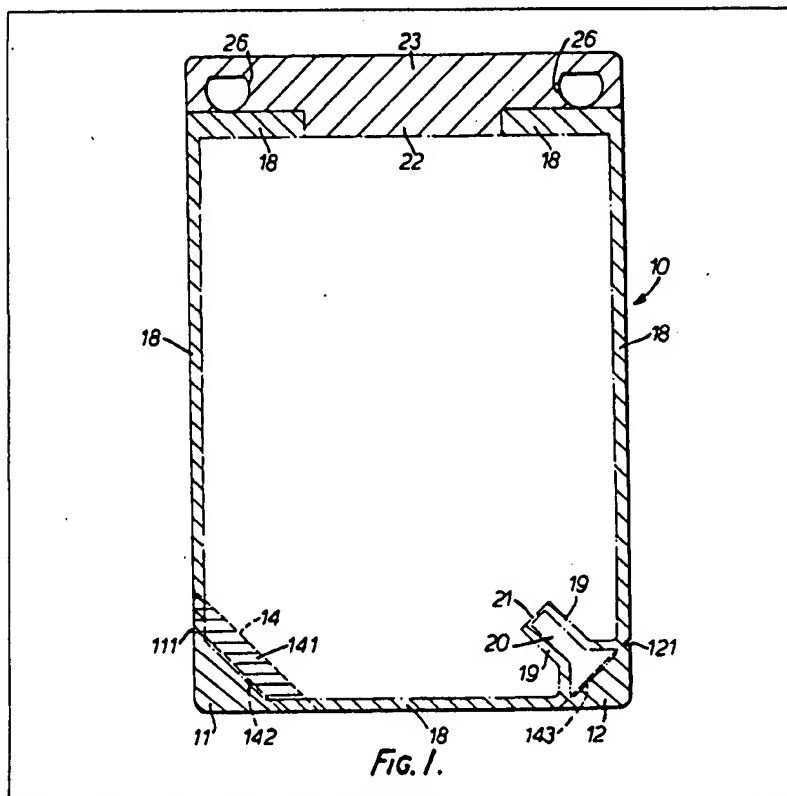


Fig. 1.

The drawings originally filed were informal and the print here reproduced is taken from a later filed formal copy.

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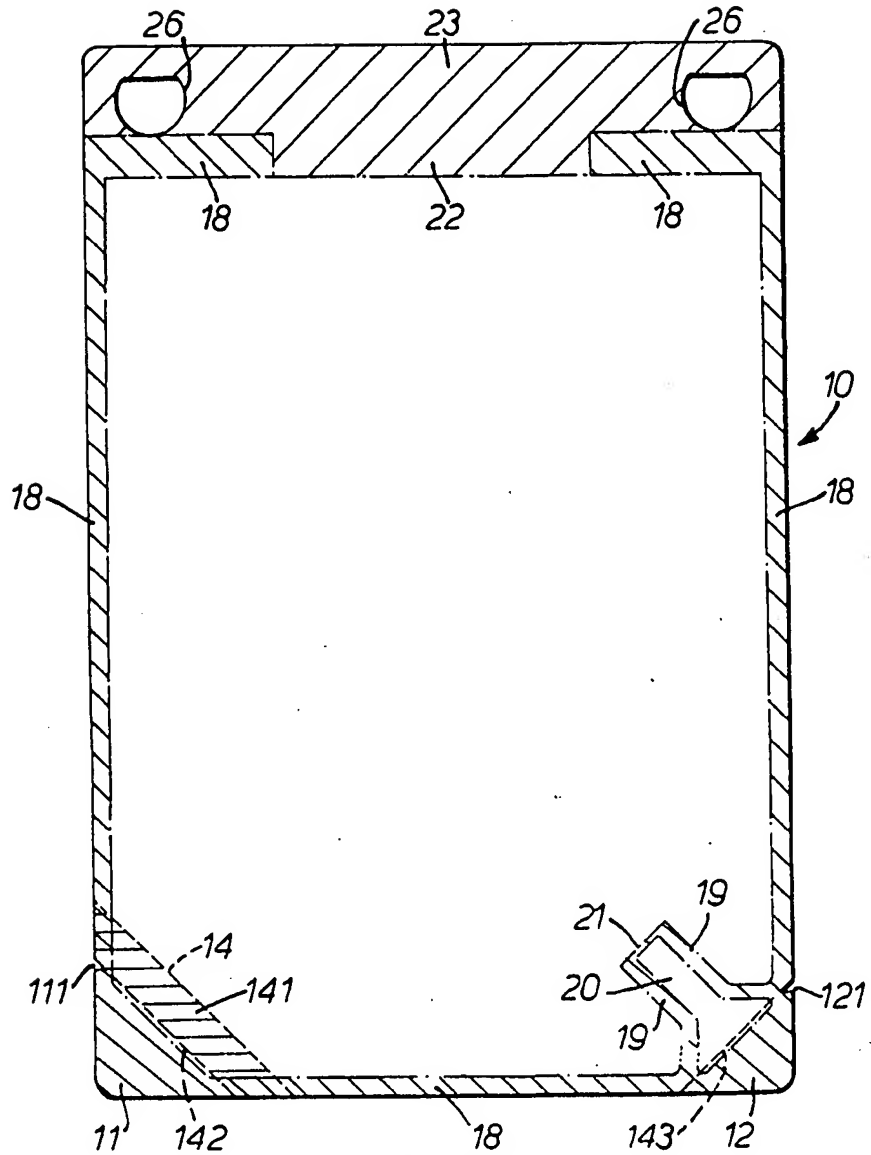


FIG. 1.

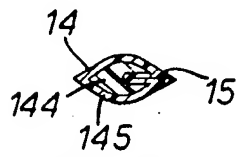


FIG. 2.

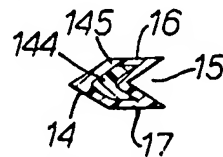
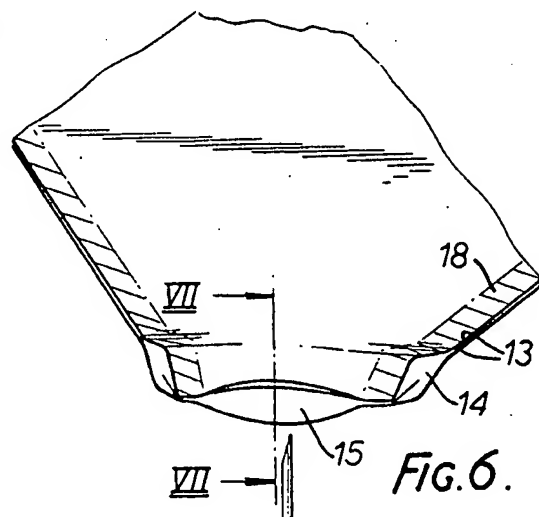
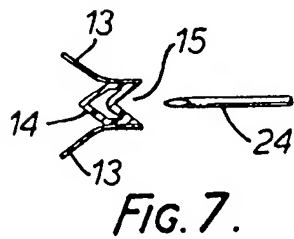
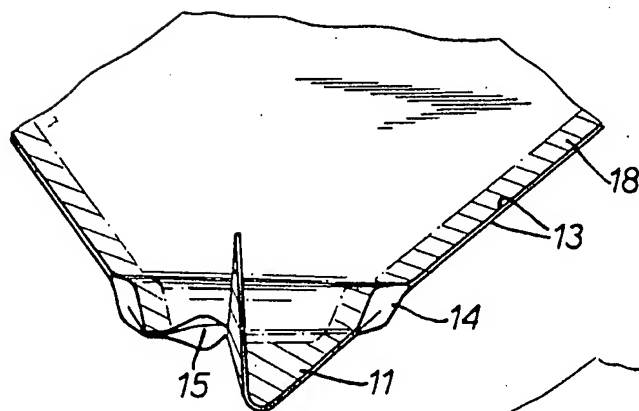
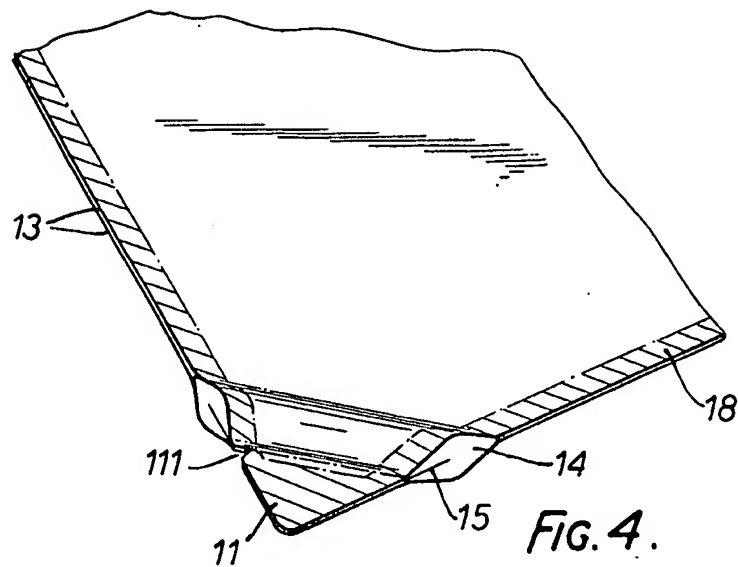


FIG. 3.

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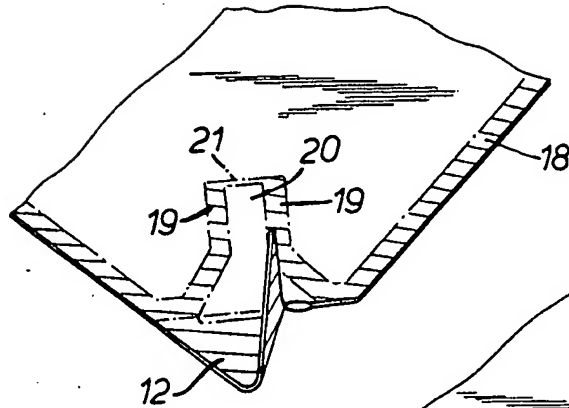


Fig. 8.

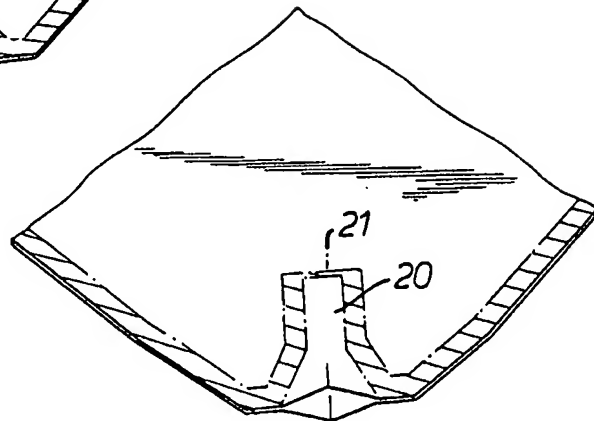


Fig. 9.

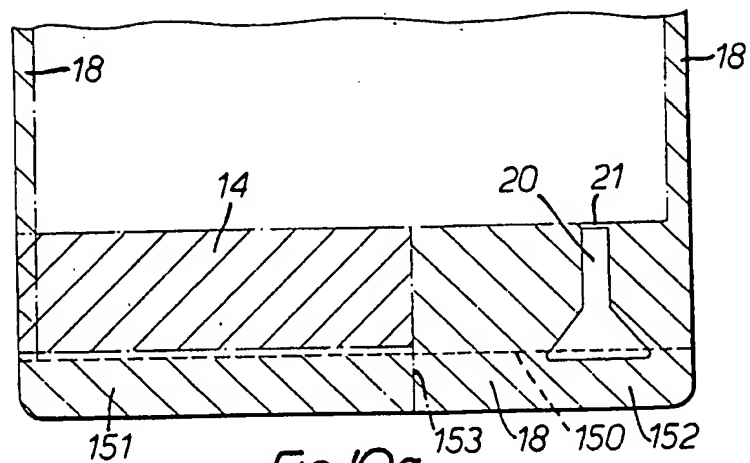
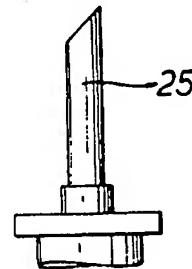


Fig. 10a

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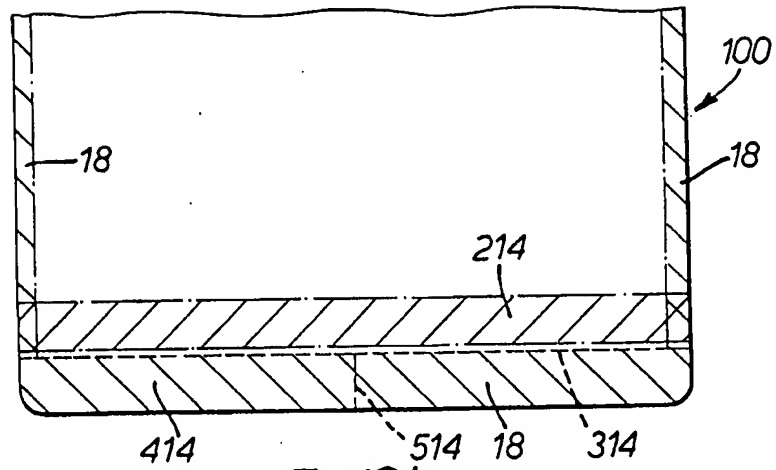


FIG. 10b

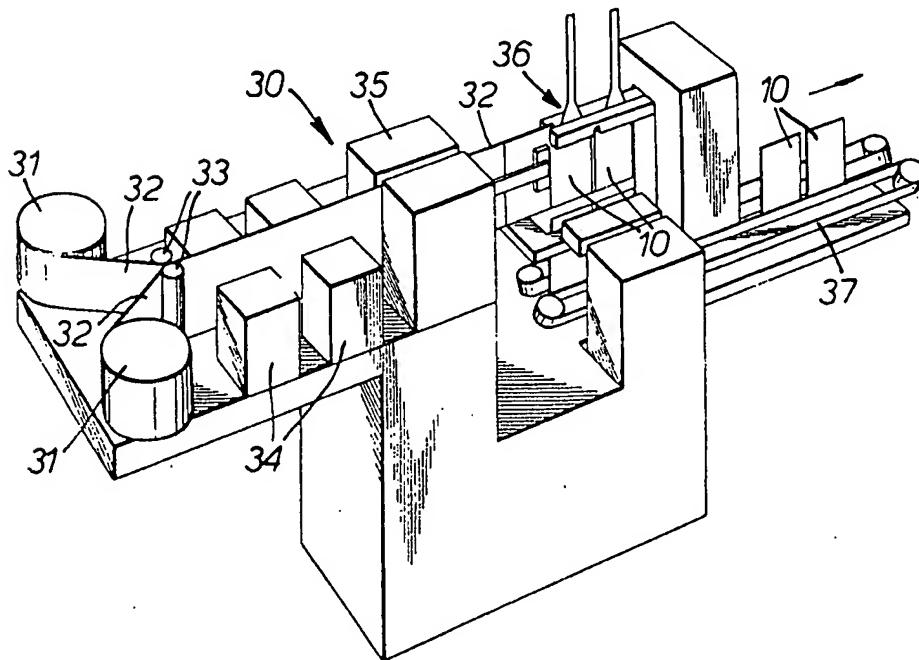


FIG. II.

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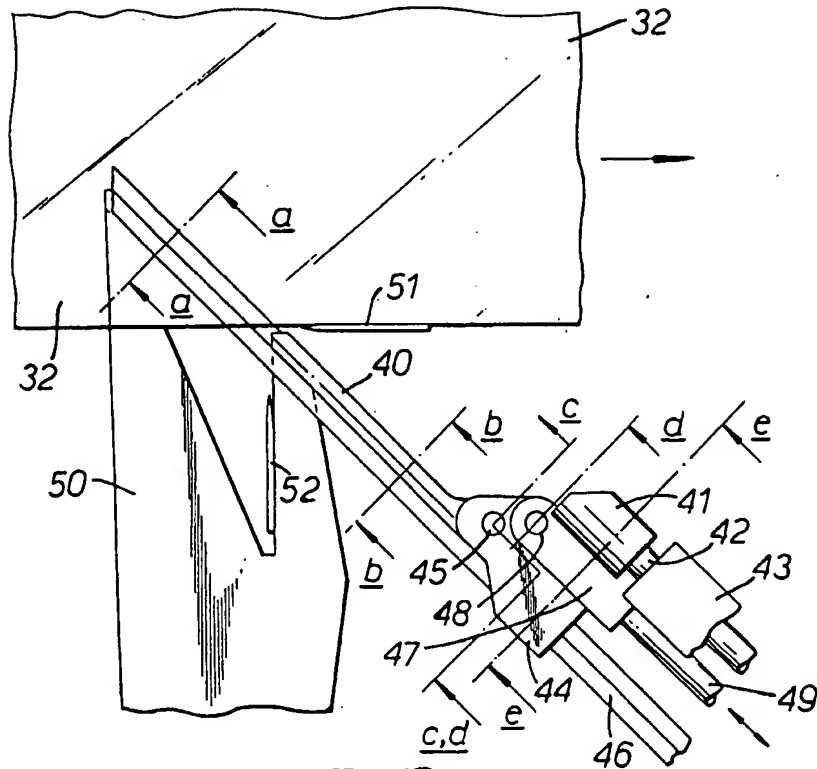


FIG. 12.

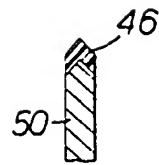


FIG. 13a



FIG. 13b

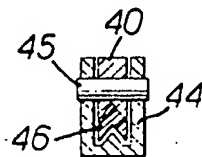


FIG. 13c

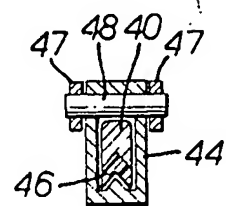


FIG. 13d

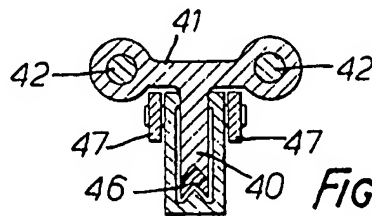


FIG. 13e

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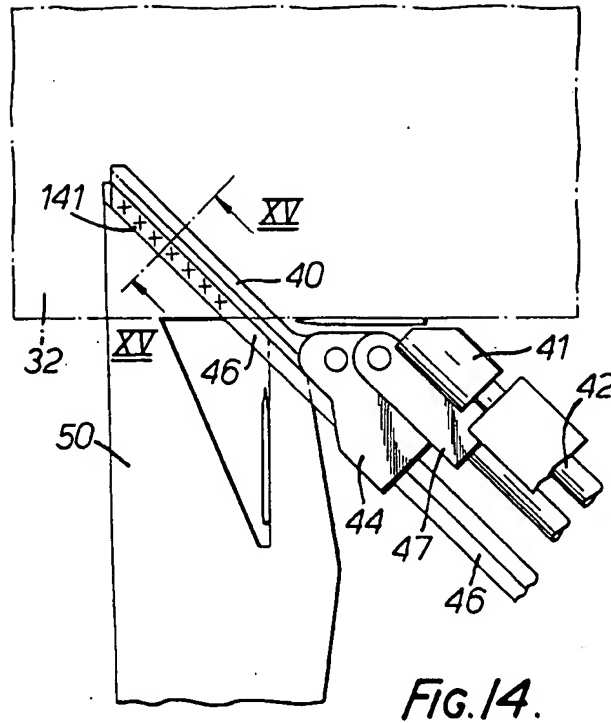


Fig. 14.

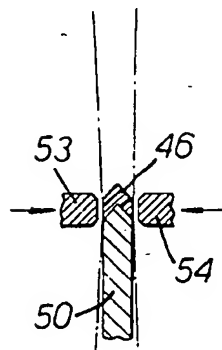
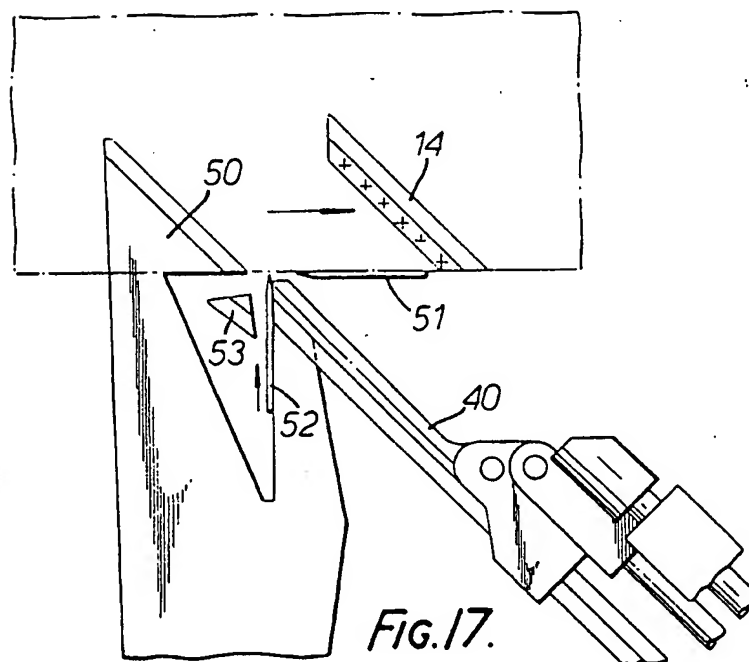
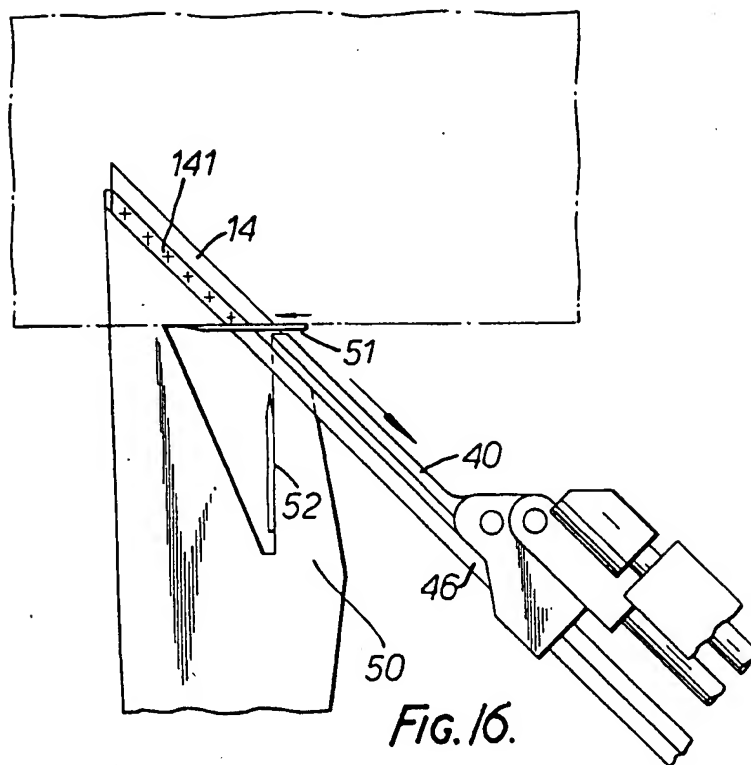


Fig. 15.

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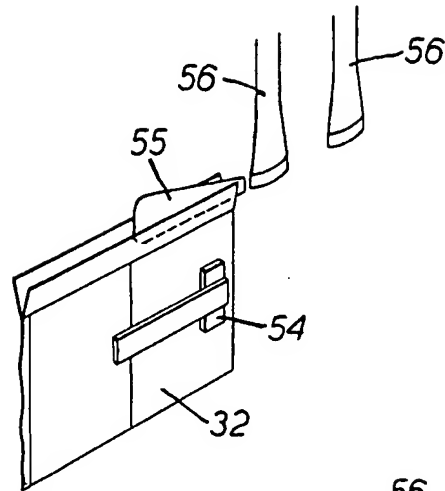


FIG. 18.

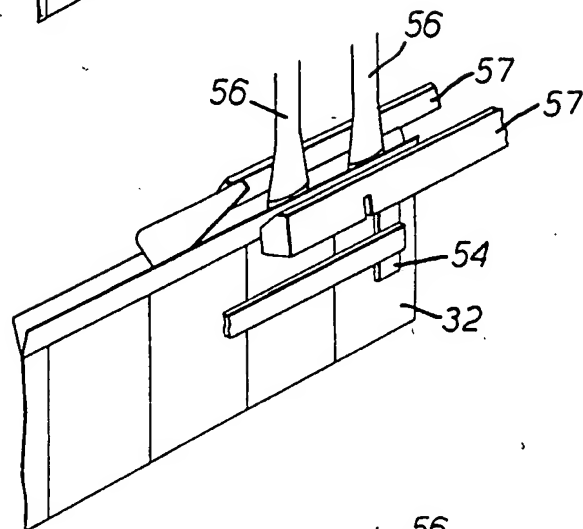


FIG. 19.

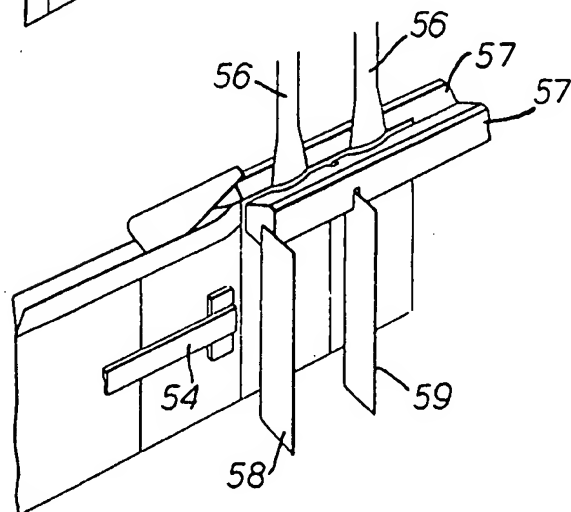
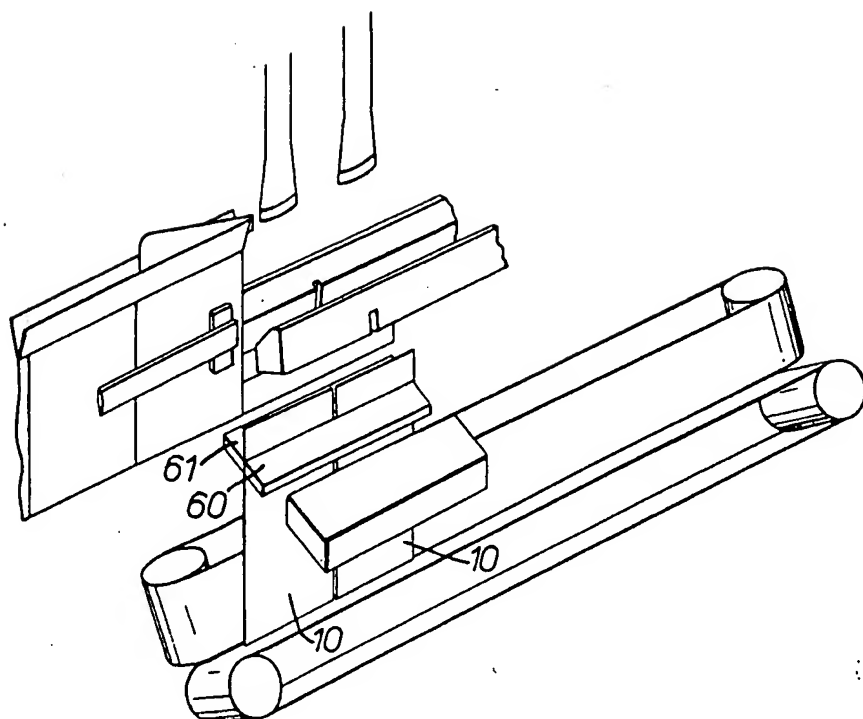


FIG. 20.

*FIG. 21.*

## SPECIFICATION

## Pouch-like bags for containing liquids

- 5 This invention relates to pouch-like bags for containing liquids for medical or surgical use, such as a liquid for intravenous injection by means of a hospital drip feed system. For such use, the bag should be capable of receiving a dispensing needle which will connect to the drip feed system, and an injection needle by which a drug can be injected into the liquid before it is administered to a patient. The formation or formations provided for this purpose should be sterile and protected from contamination.

Such bags have previously been made with tubular insert sealed into an edge portion of the bag to form ports for insertion of needles and with sealed tear-off chambers outboard of the ports, as described in British Patent Specification No. 1,544,811, for example.

It is an object of the present invention to provide an economical construction of, and method of making, such a bag, which will be especially convenient in use.

According to the present invention, there is provided a pouch-like bag for containing a liquid for medical or surgical use, the bag having two walls formed by respective plies of flexible plastics material sealed together around their periphery, wherein the bag is provided with an elongate insert of polymeric material which is capable of self-sealing a puncture made transversely through the insert, the insert being sealed between the plies of flexible material so as to extend adjacent to a portion of the bag periphery, and extreme sealed peripheral portions of the plies of flexible material outboard of the insert forming a tearable tag which, when torn off the bag, exposes at least part of the length of the said insert, along a side face thereof, so as to allow an injection or dispensing needle access to penetrate transversely through the insert and into the bag.

Advantageously each ply of flexible material has first, inner, and second, outer, layers formed respectively of linear low density polyethylene and oriented polypropylene, the first layers of the two plies being heat-sealed to one another around their periphery.

Preferably the material is weakened adjacent the insert to form a tear line along the base of the tearable tag.

In a preferred construction, the insert has a lenticular cross-section with a notch or groove facing outwards of the bag and forming a shaped portion to guide a needle into correct position for penetration transversely through the insert. The notch or groove may be held in closed position, at least at each end of the insert, by the peripheral seal of the extreme portions of the plies of plastics material, but will open on tearing off the tag. The insert

preferably has a core adapted to be easily punctured by an injection needle but to seal closely around the needle and to re-seal the puncture after withdrawal of the needle, and an outer skin suitable for heat sealing to the plies of plastics material. In a preferred example, the core is of an elastomer, a foamed polyolefin, polyolefin blend or rubber modified polyolefin, and the outer skin is of a heat sealable non-foamed polyolefin. This construction is particularly suitable for use with a hypodermic needle of the size which is used with intravenous fluid bags for injection of a drug.

The insert may extend diagonally across a substantially rectangular corner of the bag, so that the tearable tag is substantially triangular. Alternatively the insert may extend between the peripheral seals on opposite sides of the bag, substantially parallel and adjacent to the peripheral seal along a lower edge of the bag, so that the tearable tag is substantially rectangular. In the latter case, the tearable tag may be subdivided by a weakening line at right angles to the insert, so as to provide independent access to two different parts of the insert, e.g. for insertion of two different needles.

Also according to the invention, there is provided a pouch-like bag for containing a liquid for medical or surgical use, the bag having two walls formed by respective plies of flexible plastics material sealed together around their periphery, particularly a bag provided with an insert as described above, wherein the bag is formed with a pair of inward extensions of the peripheral seal between the two plies, defining a passage adapted to guide an injection or dispensing needle into the interior of the bag, and a further seal between the plies joining the inner ends of the extensions to form a frangible closure of the inner end of the passage, and extreme portions of the plies of flexible material which extend outboard of the passage are sealed together so as to close the outer end of the passage and to form a tearable tag which, when torn off the bag, exposes the said passage. This construction is particularly appropriate for use with the needle of a conventional hospital drip feed system, which is of larger diameter than a hypodermic needle. The frangible seal may be pervious to liquids, in order to ensure that, during a preliminary sterilisation of the bag, the interior of the passage will be filled with the sterilising liquid.

The invention also resides in a method of making a pouch-like bag for containing a liquid for medical or surgical use by sealing two plies of flexible plastics material together around their periphery, wherein the method includes the steps of first sealing between the plies an elongate insert of polymeric material which is capable of self-sealing a puncture

made transversely through the insert, with said insert extending adjacent to a portion of the periphery of the plies, and subsequently effecting the peripheral seal between the plies, including sealing extreme portions of the plies together outboard of the insert to form a tearable tag which, when torn off the bag, will expose at least part of the length of the said insert, along a side face thereof.

- 10 Specific embodiments of the invention will now be described by way of example and with reference to the accompanying drawings in which:—

*Figure 1* is a plan view of a bag.

- 15 *Figure 2* is a cross-section through an insert employed in the bag of *Fig. 1*, in the compressed condition resulting from sealing of the periphery of the bag.

- 20 *Figure 3* is a similar cross-section through the insert with its notch or groove opened, as after tearing off of the corner tag.

*Figure 4* is a perspective detail view of the corner of the bag illustrating the shape of the insert.

- 25 *Figure 5* is a similar perspective detail view showing the corner tag being torn off.

*Figure 6* is a similar view showing the condition of the corner after the corner tag has been torn off.

- 30 *Figure 7* is a detail section on line VII—VII of *Fig. 6*.

*Figure 8* is a detail view of the opposite corner of the bag showing its corner tag being torn off.

- 35 *Figure 9* is a similar view showing the condition of the corner when the tag has been torn off.

*Figures 10a and 10b* are plan views of the lower parts of modified forms of bag.

- 40 *Figure 11* is a diagrammatic perspective view of a machine for forming, filling and sealing bags as illustrated in *Figs. 1 to 9*.

- 45 *Figure 12* illustrates a mechanism forming part of the machine of *Fig. 11* for placing inserts in the corners of bags as illustrated in *Figs. 1 to 9* and sealing them in position between the plies of plastics material.

- 50 *Figures 13a, 13b, 13c, 13d and 13e* are cross-sections through *Fig. 12* on lines *a-a, b-b, c-c, d-d, and e-e*, respectively.

*Figure 14* shows the mechanism of *Fig. 12* in the advanced position.

*Figure 15* is a detail sectional view of line XV—XV of *Fig. 14*.

- 55 *Figure 16* shows the mechanism after retraction, with the insert material being cut off.

*Figure 17* shows the mechanism with the leading edge of the insert strip being trimmed ready for the next operation, and

- 60 *Figures 18 to 21* show diagrammatically the operation of the filling section of the machine.

The pouch-like bag 10 illustrated in *Fig. 1* is intended for containing a liquid for medical or surgical use, such as a liquid for intrave-

nous injection which is to be dispensed by means of a conventional hospital drip feed system. The bag is accordingly provided with a formation (at its lower right-hand corner in *Fig. 1*) for connection to the drip feed system and with another formation (at its lower left-hand corner) to facilitate injection of a drug into the contents of the bag by means of a needle-equipped syringe such as a hypodermic syringe.

- 75 The bag 10 has two substantially parallel walls formed by respective plies 13 of a flexible plastics material which are capable of being heat sealed to one another. The plies 80 have substantially rectangular corners 11, 12 at the bottom of the bag. The plies 13 may be of any suitable thermoplastics material, whether of single-layer or laminated construction, which is capable of withstanding steam 85 sterilisation when filled with liquid. A preferred material is a two-layer laminated material having extrusion blown linear low density polyethylene as its inner layer and oriented polypropylene as its outer layer.

- 90 An elongate insert 14 of polymeric material is sealed into the lower left-hand corner 11 with its axis lying diagonally across the corner of the bag. When it is compressed by sealing of the edges and corners of the bag, the insert 95 14 has a lenticular cross-section, as can be most clearly seen from *Fig. 2*, with a notch or groove 15 facing outwards of the corner of the bag. Before the bag is formed, and again when the compression is released, the insert 100 14 has the cross-section shown in *Fig. 3*, with the notch or groove opened up.

- The material of the insert 14 is such that it will self-seal a puncture made transversely through it, e.g. by a conventional hypodermic 105 needle for injection of a drug into the liquid contents of the bag. Thus the insert 14 may be a multi-layer extrusion with a core 144 which is adapted to be easily punctured by an injection needle but to seal closely around the 110 needle and to re-seal the puncture after withdrawal of the needle, and with an outer skin 145 suitable for heat sealing to the plies 13 of plastics material forming the walls of the bag. Typically the outer skin 145 may be a 115 heat-sealable non-foamed polyolefin and the core 144 may be of an elastomer, foamed polyolefin, polyolefin blend or rubber modified polyolefin.

- In the manufacture of the bag, the two plies 120 13 of plastics material forming the walls of the bag are first superposed with the insert 14 between them and a first seal 141 is effected between the plies 13 and the upper and lower horizontal surfaces 16, 17 (*Fig. 3*) of the 125 insert 14. At the same time, a tear line 142 is created diagonally across the corner 11 adjacent to the insert 14 by thinning of the material of the plies 13 and a similar tear line 143 is created across the corner 12.

- 130 In the next stage of formation of the bag, a

peripheral seal 18 is effected between the two plies 13 of material around the sides, bottom and part of the upper edge of the bag 10. At the lower right hand corner 12, the seal 18 is formed with a pair of inward extensions 19 defining a passage 20 extending into the interior of the bag and a further, narrower, seal 21 joining the inner ends of the extensions 19 to form a frangible inner end of the passage 20. The outer ends of the extensions 19 diverge from one another to form a flared outer end of the passage 20. The inner seal 21 is preferably pervious to liquids so that, when the bag 10 is sterilised prior to filling, the passage 20 will receive and be sterilised by the sterilising liquid.

In the formation of the peripheral seal 18, the corner portions 11, 12 of the plies 13 are sealed together to form tearable tags, and nicks 111, 121 are formed to assist tearing. The sealing of these corner portions and of the periphery of the bag closes the outer end of the passage 20 and compresses the insert 14 along its length into the lenticular section shown in Figs. 2 and 4. The ends of the notch or groove 15 are also sealed closed at this stage and suspension holes 26 are punched out in the upper part of the bag. A gap 22 left between the ends of the seal 18 at the upper end of the bag is then used for filling the bag with liquid, after which a final top seal 23 is effected to close the gap 22 and seal the bag.

When a drug is to be added to the liquid contents of the bag 10 by means of a hypodermic syringe, the corner tag 11 is torn off as shown in Fig. 5 to expose the central part of the side-face of the insert 14. Removal of the tag 11 enables the re-entrant portion 15 in the central part of the insert 14 to open up as shown in Figs. 6 and 7 to form a mouth-shaped guide for a hypodermic needle 24 which can be readily inserted transversely through the tubular insert 14 for injection of a drug into the liquid contents of the bag 10. On withdrawal of the needle 24, the material of the insert re-seals the puncture made by the needle.

When the contents of the bag 10 are to be administered to a patient using a hospital drip feed system, e.g. for intravenous injection, a standard needle of larger size, as shown at 25 in Fig. 9, is used. The tearable corner tag 12 is first torn off, as shown in Fig. 8, to expose the passage 20 which opens up as shown in Fig. 9, as a result of pre-creasing of the plies 13 before sealing. The needle 25 is then inserted through the passage 20, which fits closely around it to prevent leakage, and through the frangible seal 21.

Fig. 10a shows a modification in which the insert 114 and the formation for forming the needle-receiving passage 20 are arranged side-by-side rather than at the corners of the bag. A tear line 150 extends across the bag

parallel to its bottom edge so as to form a tear tag 151 for the insert, and a further tear tag 152 for the passage 20. The tags 151, 152 are separable along further tear line 153 aligned with the inner end of the insert.

The needle-receiving passage 20 is formed within a heat-sealed area which includes the tear tags 151, 152 and is preferably formed at the same time as, and as part of, the peripheral heat seal 18. As with the earlier embodiment, the inner end of the passage 20 is closed by a narrow seal 21 which allows sterilising liquid to enter the passage and which is frangible by the needle of an administration set inserted into the passage after the tear tag 152 has been torn away.

Instead of using separate formations for guiding the insertion of a drug injection needle and a drip feed administration needle, respectively, in some cases it is possible to use an insert like the insert 14 for both purposes, as illustrated in Fig. 10b. In this case, the bag 100 is provided with an insert 214 of the same cross-section as the insert 14 of Figs. 2 and 3, extending between the peripheral seals 18 on opposite sides of the bag, parallel and adjacent to the seal 18 along the lower edge of the bag. The insert 214 need not extend as far as the free edges of the bag, so long as it makes a liquid-tight seal with the peripheral seal 18 to prevent loss of liquid when the tearable tag 414 is torn off. A weakening line 314 is formed adjacent the insert 214 so that the tearable tag 414 is rectangular. If desired, and as shown, the tag 414 may be subdivided by one or more further weakening lines 514 at right angles to the insert 214, so that independent access can be gained to different parts of the insert for insertion of different needles.

To form, fill and seal bags as described above, a machine as illustrated in Figs. 11 to 21 may be employed. As illustrated in Fig. 11, this machine is designed to operate on two bags simultaneously at each stage of operation, but it could equally well be adapted to work on one bag, or on more than two bags, at each stage.

The machine 30 comprises supports for two reels 31 of the plastics material from which the bags are to be made. Continuous webs 32 of the material to form the two plies 13 are drawn off in parallel from the reels 31 and pass between a pair of vertical rollers 33 to the two insert placing stations 34. The operation of stations 34 is described in more detail below with reference to Figs. 12 to 17. From stations 34, the parallel webs pass to sealing stations 35 where the peripheral seal 18 is effected in known manner. The webs 32 then pass to station 36, shown in more detail in Figs. 18 to 21, where the bags 10 are filled, sealed and separated, and finally they are discharged from the machine by a conveyor

37.

The mechanism shown in Figs. 12 to 17 for placing and sealing the tubular inserts 14 between the webs 32 comprises an elongated strip guide member 40 whose rear end carries a substantially T-section extension 41 (Figs. 12 and 13e) the ends of whose cross-member are attached to a pair of rod guides 42 slidable in fixed guides 43. A clamp member 44 is pivotally mounted on the elongated strip guide 40 by means of pin 45 and has a generally U-shaped cross-section, being shaped to embrace the underside of a strip 46 of tubular material from which the inserts 14 are to be cut. A forked driving member 47 is pivotally connected to the clamp member 44 by pin 48 and is actuated by a reciprocating rod 49. A fixed support 50 projects between the webs 32 to separate them sufficiently for insertion of the strip 46 between them and reciprocable knives 51 and 52 are provided for cutting and trimming the strip. Heat sealing bars 53, 54 (Fig. 15) are provided on each side of the fixed support 50.

In use, starting from the position shown in Fig. 12, the driving member 47 is forced up and to the left by rod 49. Because of the offset between pins 48 and 45, this causes the clamp member to pivot anti-clockwise about pin 45 and thereby to clamp the strip 46 against the strip guide 40. The leading part of the strip 46 is thus carried forward to the position shown in Fig. 14, between the webs 32. The sealing bars 53, 54 are then actuated to effect the first seal 141. The driving member 47 then withdraws the assembly as shown in Fig. 16. The effect of the offset between pins 48 and 45 is now to pivot the clamp member 44 clockwise about pin 45 and thus to release its clamping action so that the strip 46 remains in the extended position. Knife 51 is now actuated to cut the insert 14 off from the strip 46. The webs 32 now move on, as shown in Fig. 17, and knife 52 is operated to trim off the leading edge 53 of strip 46 in readiness for the next operation.

The operation of the sealing stations 35 is in accordance with known principles and will therefore not be described further.

The operation of the filling, sealing and separating station 36 is illustrated in Figs. 18 to 21. The webs 32 are advanced by a reciprocating gripper 54. A plough member 55 separates the upper edges of the webs 32, which are now divided into compartments by the seals effected at stations 35 but still retain the gaps 22 for filling. A pair of vertical filling pipes 56 then engage between the webs 32 over the gaps 22 in the two foremost compartments of the web 32 as shown in Fig. 19 and pivoted gripping bars 57 are swung in to hold the two compartments while filling takes place and the gripper 54 is withdrawn (Fig. 20). While the web 32 is in this position, 65 knives 58, 59 move in laterally to separate

the two foremost compartments from the web and thus form them into bags 10. Finally the gripping bars 57 release the bags 10 which drop down until their upper edges are gripped 70 between heated sealing bars 60, 61 which effect the final top seal 23 and thus seal the bags. The conveyor 37 then discharges the filled bags.

## 75 CLAIMS

1. A pouch-like bag for containing a liquid for medical or surgical use, the bag having two walls formed by respective plies of flexible plastics material sealed together around 80 their periphery, wherein the bag is provided with an elongate insert of polymeric material which is capable of self-sealing a puncture made transversely through the insert, the insert being sealed between the plies of flexible 85 material so as to extend adjacent to a portion of the bag periphery, and extreme sealed peripheral portions of the plies of flexible material outboard of the insert forming a tearable tag which, when torn off the bag, 90 exposes at least part of the length of the said insert, along a side face thereof, so as to allow an injection or dispensing needle access to penetrate transversely through the insert and into the bag.
2. A bag according to claim 1 wherein each ply of flexible material has first, inner, and second, outer, layers formed respectively of linear low density polyethylene and oriented polypropylene, the first layers of the 95 two plies being heat-sealed to one another around their periphery.
3. A bag according to claim 1 or 2 wherein the material of the plies of flexible material is weakened adjacent the insert to 105 form a tear line along the base of the tearable tag.
4. A bag according to any one of the preceding claims wherein the insert has a lenticular cross-section with a notch or groove 110 facing outwards of the bag and forming a shaped portion to guide a needle into correct position for penetration transversely through the insert.
5. A bag according to claim 4 wherein the 115 notch or groove is held in closed position, at least at each end of the insert, by the peripheral seal of the extreme portions of the plies of plastics material, but opens on tearing off the tag.
6. A bag according to any one of the preceding claims wherein the insert has a core adapted to be easily punctured by an injection needle but to seal closely around the needle 120 and to re-seal the puncture after withdrawal of the needle, and an outer skin suitable for heat sealing to the plies of plastics material.
7. A bag according to claim 6 wherein the core is of an elastomer, a foamed polyolefin, polyolefin blend or a rubber modified polyolefin and the outer skin is of a heat sealable 130

non-foamed polyolefin.

8. A bag according to any one of the preceding claims, wherein the insert extends diagonally across a substantially rectangular corner of the bag, so that the tearable tag is substantially triangular.

9. A bag according to any one of claims 1 to 7 wherein the insert extends between the peripheral seals on opposite sides of the bag, substantially parallel and adjacent to the peripheral seal along a lower edge of the bag, so that the tearable tag is substantially rectangular.

10. A bag according to claim 9 wherein the tearable tag is subdivided by a weakening line at right angles to the insert.

11. A pouch-like bag for containing a liquid for medical or surgical use, the bag having two walls formed by respective plies of flexible plastics material sealed together around their periphery, particularly a bag according to any one of the preceding claims, wherein the bag is formed with a pair of inward extensions of the peripheral seal between the two plies, defining a passage adapted to guide an injection or dispensing needle into the interior of the bag, and a further seal between the plies joining the inner ends of the extensions to form a frangible closure of the inner end of the passage, and extreme portions of the plies of flexible material which extend outboard of the passage are sealed together so as to close the outer end of the passage and to form a tearable tag which, when torn off the bag, exposes the said passage.

12. A bag according to claim 11 wherein the outer ends of the extensions diverge from one another to form a flared outer end of the passage.

13. A bag according to claim 11 or 12 wherein the frangible closure is pervious to liquids.

14. A bag according to any one of claims 11 to 13 wherein each ply of flexible material has first, inner, and second, outer, layers formed respectively of linear low density polyethylene and oriented polypropylene, the first layers of the two plies being heat-sealed to one another around their periphery.

15. A method of making a pouch-like bag for containing a liquid for medical or surgical use by sealing two plies of flexible plastics material together around their periphery, wherein the method includes the steps of first sealing between the plies an elongate insert of polymeric material which is capable of self-sealing a puncture made transversely through the insert, with said insert extending adjacent to a portion of the periphery of the plies, and subsequently effecting the peripheral seal between the plies, including sealing extreme portions of the plies together outboard of the insert to form a tearable tag which, when torn off the bag, will expose at least part of the

length of the said insert, along a side face thereof.

16. A method according to claim 15 wherein a leading portion of a strip of material from which the insert is to be formed is advanced into position between two continuous webs from which the two plies are to be formed, the leading portion of the strip is sealed to the two continuous webs, and is then cut off from the remaining portion of the strip.

17. A method according to claim 15 or 16 wherein the sealing of the plies around their periphery is so effected as to leave a gap at the top of the bag, and the bag is then filled with liquid through said gap.

18. A method according to claims 16 and 17 wherein the continuous webs, after the peripheral seal has been effected, are separated into individual bags only after filling of the compartments produced by the peripheral seals.

19. A method according to claim 18 wherein a final top seal is applied to the bag after its release from a filling station.

20. A pouch-like bag for containing a liquid for medical or surgical use, substantially as hereinbefore described and as illustrated in Figs. 1 to 9 of the accompanying drawings.

21. A pouch-like bag for containing a liquid for medical or surgical use, substantially as hereinbefore described and as illustrated in Figs. 10a or 10b of the accompanying drawings.

22. A method of making a pouch-like bag for containing a liquid for medical or surgical use, substantially as hereinbefore described and as illustrated in the accompanying drawings.

23. A pouch-like bag for containing a liquid for medical or surgical use, the bag having two walls formed by respective plies of a flexible plastics material sealed together around their periphery, the flexible plastics material of each ply having first, inner, and second, outer, layers respectively formed of linear low density polyethylene and oriented polypropylene, the first layers of the two plies being heat-sealed to one another to form the peripheral seal.